MC

04CO

04-09-01

#5

SECTOR / BOX SEQ

PATENT

Attorney Docket No.: A-69028/DJB/JJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Prelimnt SA MW

In re application of:

GISH et al.

Serial No. 09/747,371

Filed: December 21, 2000

For: NOVEL METHODS OF DIAGNOSING BREAST CANCER, COMPOSITIONS, AND METHODS OF SCREENING FOR BREAST CANCER MODULATORS

Examiner: UNKNOWN

Group Art Unit: 1641

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, BOX MISSING PARTS, Washington, DC 20231 on:

Dated: April 17, 2001

Signed: Marjorie Jost

Marjorie Jost

SUPPLEMENTAL RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION AND PRELIMINARY AMENDMENT RE SEQUENCE LISTING

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This Response and Amendment is intended to supplement Applicant's response mailed March 29, 2001, to the Notice to File Missing Parts of Nonprovisional Application mailed March 6, 2001. A copy of the notice is enclosed. Prior to substantive examination of the present case, Applicant offers the following amendments and remarks.

While no fee is believed to be due, the Commissioner is authorized to charge any fees including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 06-1300 (Our Order No. A-69028/DJB/JJD).

Please amend the application as follows and to comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures in adherence with rules 37 C.F.R. § 1.821-1.825:

IN THE SPECIFICATION:

Please replace the paragraph beginning at page 4, line 22, with the following rewritten paragraph:

– Figure 1 (SEQ ID NO:1) shows an embodiment of a nucleic acid (mRNA) which includes a sequence which encodes a breast cancer protein provided herein, BCO2 (SEQ ID NO:2). The start (ATG) and stop (TGA) codons are underlined, defining the open reading frame. –

Please replace the paragraph beginning at page 4, line 25, with the following rewritten paragraph:

– Figure 2 (SEQ ID NO:2) shows an embodiment of an amino acid sequence of BCO2. –

Please replace the paragraph beginning at page 4, line 29, with the following rewritten paragraph:

– Figures 4A and 4B show the alignment of human BCO2 amino acid sequence (SEQ ID NO:2) and the amino acid sequence of the mouse BCO2 ortholog (SEQ ID NO:3). –

Please replace the paragraph beginning at page 6, line 6, with the following rewritten paragraph:

– In a preferred embodiment, the breast cancer sequences are those of nucleic acids encoding BCO2 or fragments thereof. Preferably, the breast cancer sequence is that depicted in figure 1 (SEQ ID NO:1), or a fragment thereof. Preferably, the breast cancer sequences encode a protein having the amino acid sequence depicted in figure 2 (SEQ ID NO:2), or a fragment thereof. –

Please replace the paragraph beginning at page 11, line 5, with the following rewritten paragraph:

– The extracellular domains of transmembrane proteins are diverse; however, conserved motifs are found repeatedly among various extracellular domains. Conserved structure and/or functions have been ascribed to different extracellular motifs. For example, cytokine receptors are characterized by a cluster of cysteines and a WSXWS (W= tryptophan, S= serine, X=any amino acid) motif (SEQ ID NO:4). Immunoglobulin-like domains are highly conserved. Mucin-like domains may be involved in cell adhesion and leucine-rich repeats participate in protein-protein interactions. –

Please replace the paragraph beginning at page 12, line 26, with the following rewritten paragraph:

– In a preferred embodiment, the sequences which are used to determine sequence identity or similarity are selected from the sequences set forth in the figures, preferably that shown in Figure 1 (SEQ ID NO:1) and fragments thereof. In one embodiment the sequences utilized herein are those set forth in the figures. In another embodiment, the sequences are naturally occurring allelic variants of the sequences set forth in the figures. In another embodiment, the sequences are sequence variants as further described herein.

Please replace the paragraph beginning at page 13, line 18, with the following rewritten paragraph:

– Thus, "percent (%) nucleic acid sequence identity" is defined as the percentage of nucleotide residues in a candidate sequence that are identical with the nucleotide residues of figure 1 (SEQ ID NO:1). A preferred method utilizes the BLASTN module of WU-BLAST-2 set to the default parameters, with overlap span and overlap fraction set to 1 and 0.125, respectively. –

Please replace the paragraph beginning at page 41, line 15, with the following rewritten paragraph:

– In a preferred embodiment, as outlined above, screens may be done on individual genes and gene products (proteins). That is, having identified a particular breast cancer gene as important in a particular state, screening of modulators of either the expression of the gene or the gene product itself can be done. The gene products of breast cancer genes are sometimes referred to herein as "breast cancer proteins" or "breast cancer modulating proteins" or "BCMP". Additionally, "modulator" and "modulating" proteins are sometimes used interchangeably herein. In one embodiment, the breast cancer protein is termed BCO2. BCO2 sequences can be identified as described herein for breast cancer sequences. In one embodiment, a BCO2 protein sequence is as depicted in Figure 2 (SEQ ID NO:2). The breast cancer protein may be a fragment, or alternatively, be the full length protein to the fragment shown herein. Preferably, the breast cancer protein is a fragment. In a preferred embodiment, the amino acid sequence which is used to determine sequence identity or similarity is that depicted in figure 2. In another embodiment, the sequences are naturally occurring allelic variants of a protein having the sequence depicted in figure 2. In another embodiment, the sequences are sequence variants as further described herein. –

On page 60, immediately preceding the claims, please insert the enclosed text entitled "SEQUENCE LISTING".

REMARKS

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Entry of this amendment is respectfully requested. The amendments are made in adherence with 37 C.F.R. § 1.821-1.825. This amendment is accompanied by a floppy disk containing the above named sequence, SEQUENCE ID NUMBERS 1-4, in computer readable form (CRF), and a paper copy of the sequence information. The computer readable sequence listing was prepared through use of the software program "PatentIn" provided by the PTO. The information contained in the computer readable disk is identical to that of the paper copy. This amendment contains no new matter. Applicant submits that this amendment, the accompanying computer readable sequence listing, and the paper copy thereof serve to place this application in a condition of adherence to the rules 37 C.F.R. § 1.821-1.825.

Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP

Dated: April 17, 2001

James J. Diehl

James J. Diehl, Reg. No. 47,527 for
David J. Brezner, Reg. No. 24,774

Four Embarcadero Center
Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989